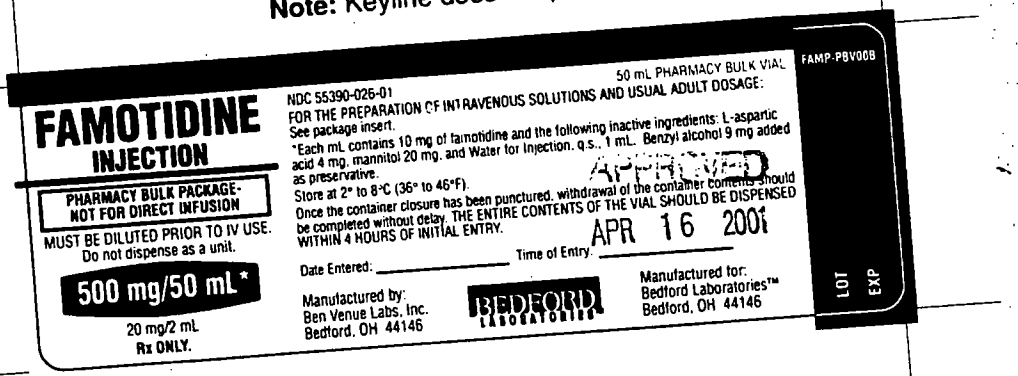
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

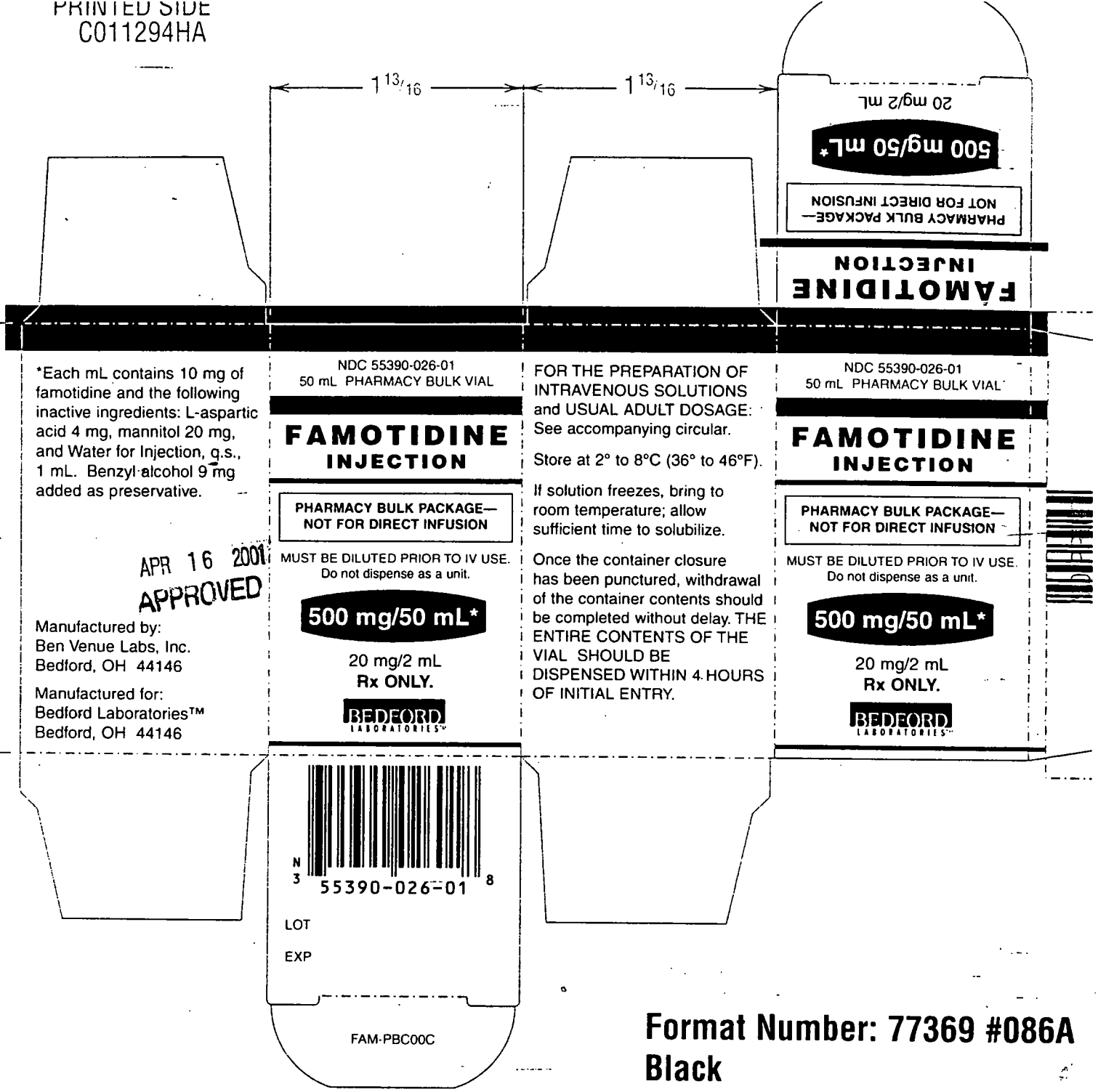
75-684

APPROVED DRAFT LABELING

Note: Keyline does not print.



PRINTED SIDE
C011294HA



*Each mL contains 10 mg of famotidine and the following inactive ingredients: L-aspartic acid 4 mg, mannitol 20 mg, and Water for Injection, q.s., 1 mL. Benzyl alcohol 9 mg added as preservative.

APR 16 2001
APPROVED

Manufactured by:
Ben Venue Labs, Inc.
Bedford, OH 44146

Manufactured for:
Bedford Laboratories™
Bedford, OH 44146

NDC 55390-026-01
50 mL PHARMACY BULK VIAL

FAMOTIDINE
INJECTION

PHARMACY BULK PACKAGE—NOT FOR DIRECT INFUSION

MUST BE DILUTED PRIOR TO IV USE.
Do not dispense as a unit.

500 mg/50 mL*

20 mg/2 mL
Rx ONLY.

BEDFORD LABORATORIES™

N 3 55390-026-01 8

LOT

EXP

FAM-PBC00C

FOR THE PREPARATION OF INTRAVENOUS SOLUTIONS and USUAL ADULT DOSAGE: See accompanying circular.

Store at 2° to 8°C (36° to 46°F).

If solution freezes, bring to room temperature; allow sufficient time to solubilize.

Once the container closure has been punctured, withdrawal of the container contents should be completed without delay. THE ENTIRE CONTENTS OF THE VIAL SHOULD BE DISPENSED WITHIN 4 HOURS OF INITIAL ENTRY.

NDC 55390-026-01
50 mL PHARMACY BULK VIAL

FAMOTIDINE
INJECTION

PHARMACY BULK PACKAGE—NOT FOR DIRECT INFUSION

MUST BE DILUTED PRIOR TO IV USE.
Do not dispense as a unit.

500 mg/50 mL*

20 mg/2 mL
Rx ONLY.

BEDFORD LABORATORIES™

Format Number: 77369 #086A
Black
478 Brown
032 Red

Prepared by
Mark Zarnstorff
Checked by

_____
_____
_____